REMARKS

Applicants thank the Examiner for the courtesy extended and helpful comments provided during the telephonic interview of November 15, 2007.

Applicants have amended Claims 15, 16, and 32. The amendments add no new matter and are fully supported by the specification and claims as originally filed. The claim amendments incorporate suggestions made by the examiner; they do not raise any new issues that would require further search; and they merely clarify the intended meaning of the claims that has already been argued to the PTO. By clarifying the claims, the amendments reduce the number of issues for appeal, and it is believed that they place the case in condition for allowance. Thus, entry after the final Office Action is appropriate..

Pending Claims 15-46 are currently presented for examination. Applicants respond below to the specific rejections set forth in Office Action dated October 22, 2007. For the reasons set forth below, Applicants respectfully traverse.

Rejection Under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claim 28, as being indefinite due to the recitation of the phrase "a 10 sample." Applicants have amended Claim 28 to replace the phrase "a 10 sample" with the phrase "a sample." Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 102(b)

Ke et al.

The Examiner has rejected Claims 15, 16, 18-21, 23-29, 31-32, 39-45 under 35 U.S.C. 102(b) as allegedly being anticipated by Ke et al (Clinical Chemistry, vol. 46, no. 3, pgs. 324-331, 2000). Applicants respectfully traverse.

Ke does not meet each and every limitation of Applicants' claims. Applicants' claimed methods require the step of adding an internal control reagent that is a cell or organelle "having at least one internal control (IC) nucleic acid target sequence therein" to a sample. The internal control reagent an test sample are processed to "release both nucleic acid[s] from said test sample and [the] IC nucleic acid target sequence from [the] internal control reagent." *Claims 15, 32.* As

such, the methods "verify the efficiency of sample preparation of test sample nucleic acids" as well as the amplification and detection procedures performed on the test sample after its preparation. *Id.*

Ke describes the use of an internal control for the amplification of nucleic acids from bacterial targets. The internal control in Ke is an isolated, purified recombinant plasmid. The internal control that is added to the sample in Ke is not a cell or organelle "having at least one internal control (IC) nucleic acid target sequence therein," as required by Applicants' claims. (Ke, page 325, column 2, heading "Construction of the Internal Control"). The test sample with the added internal control in Ke is also not subjected to a sample preparation procedure to release nucleic acids from the test sample and the internal control reagent, as required by Applicants' claims.

Because Ke does not teach every element Claims 15 16, 18-21, 23-29, 31, 32 and 39-45, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b).

Saldhana et al.

The Examiner has rejected Claims 15-17, 32 and 33 under 35 U.S.C. 102(b) as being anticipated by Saldhana, John (Journal of Clinical Virology, vol. 20, pgs. 7-13, January 2001). Applicants respectfully traverse.

Saldhana does not meet each and every limitation of Applicants' claims. As amended, Applicants' claims require the step of "providing an internal control reagent selected from the group consisting of a cell, an organelle, a parasite, a cell comprising an organelle, a cell comprising a viral particle, a cell comprising a parasite, a cell comprising a bacterial cell and any combination thereof..."

Saldhana describes lyophilized plasma in WHO International Standards for nucleic acid testing assays. The lyophilized plasma standards/controls are lyophilized preparations of plasma containing HCV, HBV, or HIV. (See Table 3, describing three different standards, and pg. 9, col. 2, lines 1-20). Plasma, by definition, is the liquid component of blood, and has no whole blood cells, or any cells. As such, the lyophilized plasma described in Saldhana is not "a cell, an organelle, a parasite, a cell comprising an organelle, a cell comprising a viral particle, a cell comprising a parasite, a cell comprising a bacterial cell and any combination thereof," and is not an internal control reagent that falls within the scope of Applicants' claims. Accordingly

Saldhana does not teach what amended independent Claims 15 and 32 require: "providing an internal control reagent selected from the group consisting of a cells, an organelle, a parasite ..."

Because Saldhana fails to meet each limitation of Claims 15-17, 32 and 33, Applicant respectfully requests that the Examiner withdraw the rejections of any claims under 35 U.S.C. § 102(b).

Rejections Under 35 U.S.C. § 102(a)

The Examiner has rejected Claims 15-21, 30, 32-34, 36, 37, and 46 under 35 U.S.C. 102(a) as allegedly being anticipated by Picard and Bergeron (Drug Discovery Today, vol. 7, iss. 2, pgs. 1092-1101, November 2002).

Picard and Bergeron does not teach each and every limitation of Claims 15-21, 30, 32-34, 36, 37, and 46. As discussed above, Applicants' claims provide methods for "verifying the efficiency of sample preparation of test sample nucleic acids" as well as nucleic acid amplification and detection procedures.

Picard and Bergeron provides a general discussion of the use of internal control for nucleic acid amplification and detection only (*See,* Picard, pg. 1099, col. 1, paragraph 2, stating that the internal controls "are designed to verify the efficiency of each amplification and/or detection reaction."). Picard and Bergeron do not teach or suggest the use of an internal control reagent that serves to control for the release, amplification and detection of nucleic acids from a test sample.

Because Picard and Bergeron does not teach every element of 15, 16-21, 30, 32-34, 36, 37, and 46, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 102(a).

Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 22 and 38 under 35 U.S.C. 102(a) as allegedly being obvious over Ke in view of Kuske et al. (Applied and Environmental Microbiology, July 1998, vol. 64, no. 7, pgs. 2463-2472). Applicants respectfully traverse.

The combined teachings of Ke and Kuske do not teach or fairly suggest each and every limitation of Claims 23 and 38. The teachings of Ke are discussed above. Kuske describes

seeding soil with *Bacillus globigii* endospores. The nucleic acids are extracted from the seeded soil (test sample), and PCR is used to detect the *B. globigii* test sample nucleic acids. (Kuske, pgs. 2464-65, "Materials and Methods" section). To control for the amplification procedure, Kuske teaches the addition of purified DNA to the purified nucleic acids of the test sample. (Kuske, pg. 2466, col. 1, "PCR assays to detect specific microbial targets" section).

Neither Ke nor Kuske teach or suggest the step of adding an internal control reagent that is a cell or organelle "having at least one internal control (IC) nucleic acid target sequence therein" to a test sample. The references neither singly or combined describe an internal reagent that can serve as a control for the release of an internal control nucleic acid target sequence.

Because Ke and Kuske do not teach or suggest each element of Claims 23 and 38, the references fail to establish that Claims 23 and 38 are *prima facie* obvious under 35 U.S.C. § 103(a). Accordingly, Applicants respectfully request withdrawal of the rejection.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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